II. Remarks

A. Status of the Claims

Claims 55-71 are currently pending. Claims 1-54 were previously canceled and claims 72-89 were previously withdrawn. Claims 55 and 57-70 have been amended herein without prejudice. Support for the amendments can be found throughout the application as originally filed, specifically at, e.g., page 4, lines 4-9, page 13, lines 12-14 and in the originally filed claims. The Applicants respectfully submits that no new matter has been added by virtue of this amendment.

B. Objection to the Specification

In the Office Action, the disclosure was objected to for not reciting the numerical patent no. following the words "U.S. Patent No."

In response, the specification has been amended to recite "U.S. Patent No. 6,673,351". Accordingly, the Examiner is requested to withdraw the objection.

C. Sequence Compliance

In the Office action, the Examiner stated that the specification fails to comply with the requirements of 37 C.F.R. 1.821-25 as the sequence identifiers must be inserted into the body of the specification directly following the sequence. The Examiner directed the Applicant to Table 18 on pages 39-40 as failing to recite the corresponding sequence identification numbers.

In response, Table 18 has been replaced with a new table which includes the sequence identifiers following the sequences. Accordingly, the Examiner is requested to withdraw the rejection.

D. Double Patenting Rejections

In the Office Action, claims 55-71 were rejected on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,673,351.

In response, the Applicant submits a properly executed Terminal Disclaimer over U.S. Patent No. 6,673,351.

The Applicant notes that the filing of a Terminal Disclaimer is not an admission, acquiescence or estoppel on the merits of an issue of obviousness. See *Quad Environment Technologies Corp. v. Union Sanitary District*, 946 F.2d 870, 873-74, 20 U.S.P.Q. 2d 1392, 1394-95 (Fed. Cir. 1991).

Accordingly, Applicants respectfully request that the double patenting rejection be removed.

E. Rejections under 35 U.S.C. 112-2nd paragraph

In the Office Action, claims 55-71 were rejected under 35 U.S.C. § 112, second paragraph, on the grounds of "being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

Specifically, claim 55 was rejected o the grounds of "being unclear what is encompassed by the term 'particulate antigen.'" In response, this term has been deleted from the pending claims without prejudice.

Claim 55 was also rejected on the grounds of reciting "that the antigen is isolated from *Leishmania* protozoa yet the specification teaches that the extract comprises polypeptides of this molecular weight are specifically isolated from amastigotes" and that "the molecular weights of the components in the mixture which may come from any protozoa of genus *Leishmania* ... is not sufficient to satisfy the statute's requirement of adequately describing and setting forth the inventive concept." The Examiner suggested that the claims should provide structural properties such as the amino acid sequence of the polypeptides.

In response, in accordance with the Examiner's suggestion, claim 55 has been amended to recite the amino acid sequence of the polypeptides. The Applicant further notes that claim 55 has been amended without prejudice to delete the molecular weight recitations making the above

rejection moot.

Claims 57 and 58 were rejected on the grounds of being indefinite "due to the parentheticals, e.g., (V), (L) and the misspelling 'basiliensis.'"

In response, claims 57 and 58 have been amended without prejudice in accordance with the Examiner's suggestion to delete the parentheticals and to correct the misspelling.

Claims 59-70 were rejected on the grounds of being indefinite for reciting the term "immunogenic variants."

The Applicant respectfully directs the Examiner's attention to page 2, lines 24 to page 3, line 4, which defines "immunogenic variant" as follows:

> *An immunogenic variant of an amino acid sequence ay be either a truncated version of the sequence that retains a substantial amount of the activity of the original, or a altered version of the sequence retaining such activity and having conservative amino acid substitutions and/or modifications.*

Although the Applicant believes that one skilled in the art would be able to determine the meets and bounds of the claim limitation "immunogenic variant", the claims have been amended without prejudice to delete the phrase "or immunogenic variants thereof" in order to expedite prosecution of the application.

Finally, claims 59-70 were rejected on the grounds of being indefinite "because it is unclear which sequence identification numbers correspond to which molecular weight."

In response, the Applicant has amended the claims without prejudice to cancel the limitations directed to molecular weights

In view of the actions taken, the Examiner is respectfully requested to remove the rejections under 35 U.S.C. § 112, 2nd paragraph.

F. Rejections under 35 U.S.C. 112-Enablement

In the Office Action, claims 55-71 were rejected under 35 U.S.C. § 112, first paragraph, on the grounds of being non-enabled for "a composition for treatment of symptoms of psoriasis comprising *any* particulate antigen isolated from protozoa of genus *Leishmania,* wherein the particulate antigen comprises polypeptides having apparent molecular weights after total reduction and alkylation of 73 kDa, 80 kDa, and 82 kDa."

Although the Applicant disagrees with the Examiner's rejection, the claims have been amended without prejudice to be directed to the specific polypeptides of any of SEQ ID Nos. 1-14. Therefore, the claims are not directed to *any* particulate antigen having apparent molecular weights of 73 kDa, 80 kDa, and 82 kDa as previously recited.

The claims were further rejected on the grounds of being non-enabling for "immunogenic variants" of SEQ ID Nos. 1-14. As discussed above, although the Applicant believes that one skilled in the art would be able to readily determine such variants of SEQ ID Nos. 1-14, the claims have been amended to delete the phrase "or immunogenic variants thereof" in order to expedite prosecution of the application.

In view of the actions taken, the Applicant respectfully requests that the enablement rejections under 35 U.S.C. § 112 be removed.

G. Rejections under 35 U.S.C. 112-Written Description

In the Office Action, claims 55-71 were rejected under 35 U.S.C. § 112, first paragraph, on the grounds of failing to comply with the written description requirement. The Examiner stated that the written description only sets forth " 'a composition capable of eliciting an immune response to result in abatement of the clinical symptoms of psoriasis, said composition comprising a purified protein extract wherein said purified protein extract is isolated by diethylaminoethyl Sephadex chromatography of a Nonidet P-40 insoluble particulate antigen fraction obtained from isolated killed cells of amastigotes from at least on species of the Leishmania genus, said particulate antigen fraction solubilized with 8 M urea and 0.025 M Tris[hydroxymethyl]aminomethane pH 8.3 applied to diethylaminoethyl Sephadex and eluted

with a solution comprising 0.1 M sodium chloride, 8 M urea and 0.025M Tris[hydroxymethyl]aminomethane pH 8.3, said purified protein extract consisting of polypeptides having an apparent molecular weights after total reduction and alkylation of 73, 80 and 82 kDa". (Emphasis added).

In response, the claims have been amended without prejudice to be directed to the specific polypeptides of any of SEQ ID Nos. 1-14, as suggested by the Examiner. Therefore, the claims are not directed to *any* particulate antigen having apparent molecular weights of 73 kDa, 80 kDa, and 82 kDa as previously recited. The Applicant respectfully submits that the amended claim meets the written description requirement as the specification provides an adequate description of the particular sequences of the designated polypeptides.

Additionally, the Examiner stated that "the instant specification fails to describe any immunogenic variants of the amino acid sequences set forth in SEQ ID Nos. 1-14."

As discussed above, although the Applicant submits that the specification does provide a written description for "immunogenic variants" of any of SEQ ID Nos. 1-14 at page 2, line 24 to column 3, line 4, the claims have been amended without prejudice to delete the phrase "or immunogenic variants thereof" in order to expedite prosecution of the application.

In view of the actions taken, the Applicant respectfully requests that the written description rejection under 35 U.S.C. § 112 be removed.

H. Rejections under 35 U.S.C. 102(b)

In the Office Action, the Examiner rejected the claims under 35 U.S.C. § 102(b) on the grounds of being anticipated by Gac. Med. Caracus 103(2): 133-177, 1995 ("the O'Daly reference").

The Applicant respectfully submits that the present claims have been amended without prejudice to be directed to, in pertinent part, a composition comprising (i) polypeptides isolated from protozoa of genus *Leishmania* in a therapeutically effective amount to treat psoriasis and (ii) a pharmaceutically acceptable carrier. The Applicant respectfully submits that the O'Daly

reference does not teach or suggest a composition comprising polypeptides in a therapeutically effective amount to treat psoriasis, let alone a composition comprising a therapeutically effective amount of any of SEQ ID Nos. 1-14 to treat psoriasis. Accordingly, the Applicant respectfully requests withdrawal of the anticipation rejection over the O'Daly reference.

I. Rejections under 35 U.S.C. 102(e)

In the Office Action, the Examiner rejected the claims under 35 U.S.C. § 102(e) on the grounds of being anticipated by U.S. Patent No. 6,458,581 ("the Lemesre reference")

The Applicant respectfully submits that the Lemesre reference also does not teach or suggest a composition comprising polypeptides in a therapeutically effective amount to treat psoriasis, let alone a composition comprising a therapeutically effective amount of any of SEQ ID Nos. 1-14 to treat psoriasis. Accordingly, the Applicant respectfully requests withdrawal of the anticipation rejection over the O'Daly reference.

IV. Conclusion

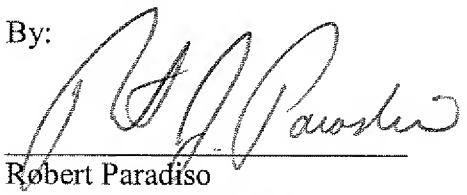
Applicant earnestly solicits early and favorable action by the Examiner. If the Examiner believes that issues may be resolved by a telephone interview, the Examiner is respectfully urged to telephone the undersigned at (973) 597-2590. The undersigned also may be contacted via e-mail at rparadiso@lowenstein.com.

AUTHORIZATION

The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account No. 50-1358.

Respectfully submitted,

Lowenstein Sandler PC

By: 

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